Exhibit G

Amide
PHARMACEUTICAL, INC.
101 EAST MAIN STREET LITTLE FALLS, NJ 07424 USA

ANDA - 40-282 2/21/05

ANNUAL REPORT
1/1/04 - 12/31/04

DIGOXIN TABLETS, USP
0.125 mg and 0.25 mg

AMIDE COPY

TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS FOR HUMAN USE (21 CFR 314.81)

DATE SUBMITTED: 2/21/2005

Form Approved: OMB No. 0910-0002
Expiration Date: March 31, 2005
See OMB Statement on Reverse.

NOTE: This report is required by law (21 USC 355; 21 CFR 314.81). *Failure to report can result in withdrawal of approval of the New Drug Application.*

1. NDA OR ANDA NUMBER: N 4 0 2 8 2

INSTRUCTIONS

Complete a transmittal form for each application for which an annual report is being submitted. Retain the carbon copy labeled "applicant." Submit the remaining copies of the transmittal form along with two copies of the annual report to FDA.

If any part of the annual report applies to more than one application, list in Item 7 all other applications to which such parts apply.

2. Report No. *(FDA Complete)*: Y- 0 0 5

APPLICANT NOTE

Reference NDA and Y numbers *(entered on Acknowledgement Copy)* in any subsequent correspondence regarding report.

4. APPLICANT: AMIDE PHARMACEUTICAL, INC.

PHONE NUMBER: (973) 890-1440

3. CFR SECTION NUMBER *(Antibiotic only)*:

5. DRUG NAME: DIGOXIN TABLETS, USP 0.125 mg and 0.25 mg

6. TYPE OF REPORT *(Check one)*: ☒ ANNUAL ☐ OTHER

7. OTHER NDA/ ANTIBIOTIC APPLICATION NUMBERS *(List all numbers if any part of report applies to more than one number.)*:

8. PERIOD COVERED BY REPORT

FROM		TO	
YEAR	MONTH	YEAR	MONTH
2004	01	2004	12

Fold Line

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9. REPORT INFORMATION REQUIRED *(See § 314.81 for description)*
(Enter type of information attached under "Identification." If you have nothing to report, enter None.)
(INFORMATION IN "9b" AND "9c" IS ALWAYS REQUIRED.)

TYPE OF INFORMATION	IDENTIFICATION *(Volume No.(s) / Tab(s) / Page(s) of Report)*
a. SUMMARY OF SIGNIFICANT NEW INFORMATION	NONE
b. DISTRIBUTION DATA	ENCLOSED
c. LABELING *(Whether or not previously submitted)*	ENCLOSED
d. CHEMISTRY MANUFACTURING AND CONTROLS CHANGES ☒ SUPAC	Extension of expiration period to 3 years based on 3 batch room temperature data. Attachment 4.
e. NONCLINICAL LABORATORY STUDIES	NONE
f. CLINICAL DATA	NONE
g. STATUS REPORT POST-MARKETING STUDIES	NONE
h. STATUS OF OPEN REGULATORY BUSINESS *(Optional)*	NONE

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Fold Line

TYPED NAME AND TITLE OF RESPONSIBLE OFFICIAL OR AGENT
JASMINE SHAH, M.S., R.Ph.
DIRECTOR, REGULATORY AFFAIRS

SIGNATURE

APPLICANTS RETURN ADDRESS *(Type within the window envelope tic marks)*

JASMINE SHAH
AMIDE PHARMACEUTICAL INC.
101 EAST MAIN STREET, LITTLE FALL, NJ 07242

FDA USE ONLY

10. NDA OR ANDA NUMBER: N 4 0 2 8 2

11. DATE OF RECEIPT

RECEIVED
FEB 22 2005
OGD / CDER

FORM FDA 2252 (4/02) PREVIOUS EDITION IS OBSOLETE.

00 [redacted]

Amide PHARMACEUTICAL, INC.
101 East Main Street
Little Falls, New Jersey 07424
Telephone (973) 890-1440
Fax (973) 890-7980

February 21, 2005

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Metropark North II
7500 Standish Place, Room 150
Rockville, MD 20855-2773.

Re: Annual Reporting of ANDA 40-282
Digoxin Tablets, USP 0.125 mg and 0.25 mg

Dear Mr. Buehler:

In reference to the submission of "Transmittal of Periodic Reports for Drugs for Human Use" for **Digoxin Tablets, USP 0.125 mg and 0.25 mg**, enclosed please find form FDA 2252 **(Attachment 1)** and the necessary documents. This report covers period from January 1, 2004 to December 31, 2004.

COMPLAINTS: A total of nineteen (19) complaints were received for these products during the reporting period. Enclosed please find a complaint summary **(Attachment 2).**

STABILITY: Pertinent room temperature stability data for the following batches tested during the reporting period is enclosed **(Attachment 3):**

Digoxin Tablets, USP 0.125 mg

100's (metal cap) - 1095A
5000's (metal cap) - 1095A

100's (plastic cap) - 1290A, 1291A, 1292A, 2319A1, 3463A1, 4076A
5000's (plastic cap) - 1290A1, 1291A1, 1292A, 2319A, 3463A, 4076A1

Digoxin Tablets, USP 0.25 mg

100's (metal cap)- 1108A
5000's (metal cap)- 1108A

100's (plastic cap)- 1288A1, 1331A, 1332A, 2331A, 3490A1
5000's (plastic cap)- 1288A, 1331A1, 1332A1,2331A1, 3490A

FD&C Green Lake Blend LB-603: Raw material analytical method was revised on March 15, 2004 to change Identification test as per FDA color additive certification method. Enclosed please find revised copy of method and specifications for FD&C Green Lake Blend LB-603 **(Attachment 7)**.

There were no changes in the analytical methods from that submitted earlier.

MANUFACTURING AND CONTROL CHANGES:

There were no changes made in manufacturing and control procedures for these products during reporting period.

Digoxin Tablets, USP 0.125 mg
A total of forty two (42) batches of Digoxin Tablets, USP 0.125 mg were manufactured during the reporting period. Batch #'s 4076A, 4077A, 4151A, 4152A, 4153A, 4154A, 4155A, 4232A, 4234A, 4235A, 4236A, 4237A, 4275A, 4276A, 4277A, 4278A, 4279A, 4366A, 4367A, 4368A, 4369A, 4370A, 4412A, 4413A, 4414A, 4440A, 4441A, 4442A, 4443A, 4444A, 4606A, 4607A, 4610A, 4611A, 4612A, 4637A, 4638A, 4639A, 4640A, 4641A, 4661A, and 4662A were 4,800,000 tablets batch size each. Equipment comparable to the submission batch was used to manufacture these batches.

Digoxin Tablets, USP 0.25 mg
A total of thirty six (36) batches of Digoxin Tablets, USP 0.25 mg were manufactured during the reporting period. Batch #'s 4183A, 4184A, 4185A, 4186A, 4187A, 4301A, 4302A, 4303A, 4304A, 4305A, 4325A, 4331A, 4333A, 4334A, 4335A, 4336A, 4451A, 4452A, 4453A, 4454A, 4486A, 4487A, 4488A, 4489A, 4490A, 4582A, 4692A, 4693A, 4694A, 4695A, 4696A, 4731A, 4732A, 4733A, 4734A, and 4735A were 4,200,000 tablets batch size each. Equipment comparable to the submission batch was used to manufacture these batches.

PACKAGING AND DISTRIBUTION CONTROLS:

A CBE-30 supplement for alternate packaging and labeling site was submitted on November 4th, 2004 and approved on January 13th, 2005.

There were no other changes made in packaging and distribution controls for these products during the reporting period.

TRANSMITTAL OF ANNUAL REPORTS FOR DRUGS FOR HUMAN USE (21 CFR 314.81)

DATE SUBMITTED: 02/21/05

Form Approved: OMB No. 0910-0001
Expiration Date: March 31, 2005
See OMB Statement on Reverse.

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FDA USE ONLY

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11. DATE OF RECEIPT

FORM FDA 2252 (4/02) PREVIOUS EDITION IS OBSOLETE.

00 [redacted]

Digoxin Tablets, USP 0.125 and 0.25 mg
Complaint Summary 1/1/2004 to 12/31/2004

A total of nineteen (19) complaints were received during January 2004 to December 2004 reporting period. The complaints received, were noted as:

	COMPLAINT	COMPLAINT SUMMARY
1.	Dizziness	Known adverse effect
2.	Fatigue, dizziness, diarrhea	Known adverse effects
3.	Increased blood pressure	Known adverse effect
4.	Nausea	Known adverse effect
5.	Contamination	Metal object seen in tablet
6.	Thick tablet	Tablet was left in the vibrator during the set up of the machine and passed undetected.
7.	Dispensing Error	Dispensing error by pharmacist
8.	Weight Loss	Unknown adverse effect
9.	Hair loss	Unknown adverse effect
10.	Black deposits on teeth	Unknown adverse effect
11.	Fast dissolution of the tablets	Incorrect administration of the product
12.	Hypophosphatemia and leucopenia	Patient was receiving multiple medications and was enrolled on new drug investigational study. Patient might experience drug interaction effect.
13.	Products mix-up	Dispensing error by pharmacist
14.	Short count (30 tablets short)	One month supply was dispensed before
15.	Nausea	Known adverse effect
16.	Products mix-up	Dispensing error by pharmacist
17.	Palpitation	Known adverse effect
18.	Blurred vision	Known adverse effect
19.	Short Count (empty bottle)	Isolated incident. Extremely rare case